IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AZURITY PHARMACEUTICALS, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Bristol-Myers Squibb Company ("BMS") and Pfizer Inc. ("Pfizer") (BMS and Pfizer, collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. Plaintiffs are two of the leading innovative pharmaceutical companies in the world, with a deep commitment to discovering new lifesaving drugs and delivering them to patients.

2. This case relates to the Plaintiffs' blockbuster drug Eliquis® (apixaban), which has helped tens of millions of patients and is celebrated as one of the world's most successful drugs. Approved by the U.S. Food and Drug Administration ("FDA") in 2012, Eliquis® has proven safe and effective for, *inter alia*, reducing the risk of stroke and systemic embolism and for treating deep vein thrombosis and pulmonary embolism. Both the unique active ingredient and the unique formulation of Eliquis® have contributed to the drug's success.

3. The FDA's Orange Book lists two patents for Eliquis®: U.S. Patent No. 6,967,208 ("the '208 patent"), which protects the active ingredient apixaban and, with its

applicable pediatric exclusivity, expires in May 2027, and U.S. Patent No. 9,326,945 ("the '945 patent," Ex. A), which protects formulations of apixaban and, with its applicable pediatric exclusivity, expires in August 2031.

4. Seeking to benefit from Plaintiffs' investments, inventions, and data, multiple companies previously filed drug applications with the FDA for approval of apixaban products prior to expiration of the '208 and '945 patents. Plaintiffs accordingly initiated litigation under the Hatch-Waxman framework and, after a bench trial, won in 2020, *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, 477 F. Supp. 3d 306, 311 (D. Del. 2020), and on appeal to the Federal Circuit in 2021, *Bristol-Myers Squibb Co. v. Sigmapharm Labs., LLC*, 858 F. App'x 359 (Fed. Cir. 2021).

5. Defendant Azurity Pharmaceuticals, Inc. ("Azurity" or "Defendant") now also seeks to benefit from Plaintiffs' investments, inventions, and data, by requesting FDA approval of apixaban products prior to expiration of the '945 patent (but not the '208 patent). More specifically, upon information and belief, Azurity filed with the FDA a drug application under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2) ("Azurity's 505(b)(2) Application"), seeking approval to market apixaban products ("Azurity's 505(b)(2) Products"), and included with that application a paragraph IV certification as to the '945 patent.

6. In view of Azurity's paragraph IV certification and information about Azurity's 505(b)(2) Products that is currently available to Plaintiffs, Plaintiffs bring this action against Azurity for infringement of the '945 patent.

PARTIES

7. BMS is a corporation organized and existing under the laws of Delaware, having a principal place of business at Route 206 and Province Line Road, Princeton, New Jersey 08543.

8. Pfizer is a corporation organized and existing under the laws of Delaware, having a principal place of business at 66 Hudson Boulevard East, New York, New York 10001.

9. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary pharmaceutical products to help patients prevail against serious diseases, including treatments for thromboembolic disorders. Plaintiffs sell Eliquis® in this judicial district and throughout the United States.

10. Upon information and belief, Azurity is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 8 Cabot Road, Suite 2000, Woburn, Massachusetts 01801.

JURISDICTION AND VENUE

11. This case arises under the patent laws of the United States of America, 35 U.S.C. §§ 100 et seq., and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has personal jurisdiction over Azurity because, *inter alia*, Azurity is a Delaware corporation.

13. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Azurity is incorporated in Delaware and therefore resides in this judicial district.

DEVELOPMENT OF ELIQUIS®

14. For more than 50 years, warfarin was the only FDA-approved oral anticoagulant, but the drug had significant drawbacks that limited its usefulness. For example, warfarin interacts with common foods and other drugs and also has a narrow therapeutic window, which complicates dosing the drug effectively. Dozens of leading pharmaceutical companies tried to develop alternatives to warfarin without success. BMS scientists prepared and screened thousands of compounds before discovering apixaban in the early 2000s.

15. Having a compound does not equate to having a drug that is ready for patients. So, even after discovering apixaban, Plaintiffs undertook additional years of research and development before arriving at a drug that could be safely and effectively administered to patients. During clinical trials, Plaintiffs' scientists observed unexpectedly diminished apixaban exposure using certain formulations of the compound. After further work and investigation, they determined that apixaban's bioavailability is dissolution-rate limited and that maintaining a dissolution rate where at least 77% of the apixaban (by weight) dissolved in 30 minutes achieved consistent absorption. Plaintiffs' scientists determined that they could consistently accomplish their desired dissolution rate if 90% of the crystalline apixaban particles had a diameter less than or equal to 89 μm—*i.e.*, if the particle size of the crystalline apixaban had a "D_{90}" less than or equal to 89 μm. By developing apixaban formulations with that particle size and dissolution profile, Plaintiffs' scientists achieved a means for safely and effectively administering apixaban, leading to the drug Eliquis®.

16. Eliquis® was approved by the FDA in December 2012, and is now marketed under New Drug Application ("NDA") No. 202155 for the following indications: (1) to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation; (2)

for the prophylaxis of deep vein thrombosis ("DVT"), which may lead to pulmonary embolism ("PE"), in adult patients who have undergone hip or knee replacement surgery; (3) for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE in adult patients following initial therapy; and (4) for the treatment of venous thromboembolism ("VTE") and reduction in the risk of recurrent VTE in pediatric patients from birth and older after at least 5 days of initial anticoagulant treatment. A copy of the prescribing information for Eliquis® is attached as Exhibit B.

PLAINTIFFS' '945 PATENT

17. On May 3, 2016, the U.S. Patent and Trademark Office duly and legally issued the '945 patent, titled "Apixaban Formulations." A true and correct copy of the '945 patent is attached hereto as Exhibit A. The claims of the '945 patent are valid, enforceable, and not expired. Plaintiffs are the joint owners of the '945 patent and have the right to enforce it.

18. The '945 patent was the subject of prior patent infringement litigation in the District of Delaware. On August 13, 2020, the Court found in favor of Plaintiffs against three defendants, holding, *inter alia*, that the '945 patent claims were infringed and not invalid. *See Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, 477 F. Supp. 3d 306, 311, 342, 354-56 (D. Del. 2020). The Federal Circuit affirmed the Court's opinion on September 3, 2021. *See Bristol-Myers Squibb Co. v. Sigmapharm Labs., LLC*, 858 F. App'x 359, 360 (Fed. Cir. 2021).

19. The '945 patent, with its applicable pediatric exclusivity, expires on August 24, 2031.

AZURITY'S 505(B)(2) APPLICATION

20. By letter dated November 12, 2025, and received by Plaintiffs via Federal Express no earlier than November 13, 2025 (the "Notice Letter"), Azurity notified Plaintiffs that

Azurity submitted its 505(b)(2) Application (No. 221024) to the FDA, seeking approval to market apixaban oral capsules, 2.5 mg and 5 mg, in reliance on Plaintiffs' investments, inventions, and data.

21. By submitting its 505(b)(2) Application and as stated in Azurity's Notice Letter, Azurity has represented to the FDA that its 505(b)(2) Products have the same active ingredient and dosage amounts as Eliquis®; that Azurity desires for the FDA to rely on Plaintiffs' Eliquis® data to approve Azurity's 505(b)(2) Products; and that Azurity's 505(b)(2) Application contains data as required to demonstrate that its 505(b)(2) Products are bioavailable and/or bioequivalent to Eliquis®.

22. Azurity's 505(b)(2) Application included a paragraph IV certification pursuant to 21 U.S.C. § 355(b) and 21 C.F.R. § 314 with respect to the '945 patent. According to its Notice Letter, Azurity alleges that its 505(b)(2) Products "will not infringe any valid and enforceable claim of the '945 Patent," and that Azurity seeks approval to engage in the commercial manufacture, use, and sale of its 505(b)(2) Products before the '945 patent expires.

23. Upon information and belief, Azurity had knowledge of the '945 patent at least as of the time Azurity submitted the paragraph IV certification in its 505(b)(2) Application.

24. Upon information and belief, Azurity did not submit a paragraph IV certification with respect to the '208 patent. Because Azurity is not challenging the '208 patent, Azurity will not receive FDA approval to market its 505(b)(2) Products before May 21, 2027, when the '208 patent expires with pediatric exclusivity.

25. Upon information and belief, Azurity intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Azurity's 505(b)(2) Products immediately and imminently upon approval of its 505(b)(2) Application.

26. This action is being commenced before the expiration of 45 days from the date Plaintiffs received the Notice Letter.

27. Counsel for Plaintiffs obtained and reviewed portions of Azurity's 505(b)(2) Application pursuant to an agreed Offer of Confidential Access. As described in more detail below, Azurity's Notice Letter, materials provided by Azurity to Plaintiffs' counsel, and publicly available information support the conclusion that Azurity infringed the '945 patent by filing its 505(b)(2) Application with a paragraph IV certification as to that patent, and that if permitted, the manufacture, marketing, and sale of Azurity's 505(b)(2) Products would infringe the '945 patent.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,326,945

28. Plaintiffs incorporate each of the preceding paragraphs 1-27 as if fully set forth herein.

29. Azurity's submission of its 505(b)(2) Application for approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Azurity's 505(b)(2) Products before the expiration of the '945 patent constituted an act of infringement of at least one claim of the '945 patent, including but not limited to claim 12, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e)(2)(A).

30. Azurity's commercial manufacture, use, offer for sale, sale and/or importation of its 505(b)(2) Products prior to expiration of the '945 patent, and Azurity's inducement of and/or contribution to such conduct, would infringe at least one claim of the '945 patent, including but not limited to claim 12, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

31. Upon FDA approval of Azurity's 505(b)(2) Application, Azurity will infringe one or more claims of the '945 patent, including but not limited to claim 12, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Azurity's 505(b)(2) Products, and/or by actively inducing and contributing to infringement of the '945 patent by others, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Azurity has notified Plaintiffs of the submission of its 505(b)(2) Application seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Azurity's 505(b)(2) Products before the expiration of the '945 patent.

32. For example, claim 12 of the '945 patent recites:

> A solid pharmaceutical composition comprising a therapeutically effective amount of apixaban and a pharmaceutically acceptable diluent or carrier,
>
> > wherein apixaban comprises crystalline apixaban particles,
> >
> > wherein the crystalline apixaban particles have a D_{90} equal to or less than about 89 μm, and
> >
> > wherein, as measured using a USP Apparatus 2 at a paddle rotation speed of 75 rpm in 900 mL, of a dissolution medium at 37°C., at least 77 wt % of apixaban in the pharmaceutical composition dissolves within 30 minutes in the dissolution medium, and the dissolution medium is 0.05 M sodium phosphate at a pH 6.8 containing 0.05% sodium lauryl sulfate.

33. The Notice Letter, materials provided by Azurity to counsel for Plaintiffs, and publicly available information support the conclusion that Azurity's 505(b)(2) Products are solid pharmaceutical compositions comprising a therapeutically effective amount of apixaban and a pharmaceutically acceptable diluent or carrier.

34. Azurity's 505(b)(2) Products comprise a solid pharmaceutical composition. The Notice Letter states that Azurity's 505(b)(2) Products are apixaban oral capsules, 2.5 mg and 5 mg. Capsules are a known type of solid pharmaceutical composition. For example, the textbook Modern Pharmaceutics states that "[c]apsules are solid dosage forms in which the drug substance is enclosed within either a hard or soft soluble shell." Ex. C, Modern Pharmaceutics at 335. FDA guidance also refers to capsules as "solid orally-administered IR [immediate-release] drug products." Ex. D, 2018 FDA Guidance at 3.

35. The 2.5 mg and 5 mg dosage amounts of apixaban in Azurity's 505(b)(2) Products are therapeutically effective amounts of apixaban. Those dosage amounts correspond with dosage amounts in Eliquis®, which is approved by the FDA for therapeutic use.

36. Azurity's 505(b)(2) Products contain a pharmaceutically acceptable diluent or carrier. The Notice Letter and Azurity's 505(b)(2) Application identify the components of Azurity's 505(b)(2) Products as the active ingredient apixaban and pharmaceutically acceptable diluents or carriers.

37. Upon information and belief, Azurity's 505(b)(2) Products contain crystalline apixaban particles. For example, upon information and belief, the manufacturing process for Azurity's 505(b)(2) Products utilizes crystalline apixaban particles that may seed the formation of crystalline apixaban particles in Azurity's 505(b)(2) Products.

38. In addition, apixaban is known to have limited solubility. For example, Azurity has reported that apixaban is a "poorly water-soluble compound." Ex. E, U.S. Patent No. 12,213,972 at 8:21-9:20. Azurity has also disclosed data regarding the "Saturation solubility of apixaban" in several solvents, which indicate the maximum amount of apixaban that may be dissolved in a given solvent under the reported conditions. *Id.* at 8:55-9:13, Table 1. Upon

information and belief, based upon Azurity's own reported solubility data for apixaban, the concentrations of apixaban in Azurity's 505(b)(2) Products indicate that the conditions within Azurity's 505(b)(2) Products allow for the formation of crystalline apixaban particles.

39. Moreover, upon information and belief, the gelatin capsule formulation utilized by Azurity may facilitate the formation of crystalline apixaban particles within Azurity's 505(b)(2) Products. For example, gelatin capsules are known in the literature to leach water into the contents of the capsule over time, causing crystallization of the solubilized drug substance encapsulated therein. Ex. F, *Water Migration from Soft Gelatin Capsule Shell to Fill Material and Its Effect on Drug Solubility*, 75 J. Pharm. Scis. 62 at 62 (1986). Azurity has described formulations in which the gelatin capsule comprises 36% water. Ex. E, U.S. Patent No. 12,213,972 at 33:25-48, Table 14. Such water leaching would reduce the solubility of apixaban and promote the formation of crystalline apixaban within Azurity's 505(b)(2) Products.

40. Materials provided by Azurity to counsel for Plaintiffs do not describe analytical testing or controls sufficient to demonstrate the absence of crystalline apixaban particles in Azurity's 505(b)(2) Products.

41. The Notice Letter, materials provided by Azurity to counsel for Plaintiffs, and publicly available information support the conclusion that crystalline apixaban particles in Azurity's 505(b)(2) Products have a D_{90} equal to or less than about 89 μm. For example, given the composition of Azurity's 505(b)(2) Products, any crystalline apixaban particles formed therein would necessarily be small in size and below the threshold D_{90} equal to or less than about 89 μm.

42. The Notice Letter, materials provided by Azurity to counsel for Plaintiffs, and publicly available information support the conclusion that Azurity's 505(b)(2) Products have

the dissolution profile claimed in the '945 patent and/or will need to have the dissolution profile claimed in the '945 patent in order to secure FDA approval.

43. Eliquis® 2.5 mg and 5 mg tablets are immediate release formulations containing apixaban and have the dissolution profile recited in claim 12 of the '945 patent.

44. Upon information and belief, Azurity intends its 505(b)(2) Products to have a similar release profile to Eliquis® in order to rely upon Plaintiffs' clinical testing for its 505(b)(2) Application.

45. Azurity has described its gel capsule formulations of apixaban, like Azurity's 505(b)(2) Products, as "immediate-release" and has stated that it specifically looked to apixaban formulations having a dissolution profile that "is comparable with the dissolution profile of commercially available immediate-release tablet formulation (Eliquis® … and NDA Number 202155)." Ex. E, U.S. Patent No. 12,213,972 at 20:33-40, 22:55-56, 23:12-13.

46. FDA issued guidance on Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances in 2018. Ex. D, 2018 FDA Guidance. This FDA guidance applies to apixaban, which is a drug classified as having high solubility under the relevant Biopharmaceutical Classification System (BCS), which evaluates the solubility of the highest therapeutic dosage amount in 250 mL of aqueous media at specified temperature and pH.

47. The FDA's 2018 guidance "applies to solid orally-administered IR [immediate-release] drug products, such as tablets and capsules, that are meant to be swallowed." *Id.* at 3. The FDA guidance provides acceptance criteria for "immediate release solid oral drug products," which is dissolution of "80% in 30 minutes." *Id.* at 5. Upon information and belief, to

satisfy the FDA guidance for an immediate release dosage form, Azurity's 505(b)(2) Products will need to have the dissolution profile recited in claim 12 of the '945 patent.

48. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '945 patent by Azurity's submission of its 505(b)(2) Application and by Azurity's desired commercial manufacture, use, and sale of its 505(b)(2) Products.

49. Upon information and belief, Azurity acted, and upon FDA approval of its 505(b)(2) Application will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '945 patent.

50. Unless Azurity is enjoined from directly or indirectly infringing the '945 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court grant the following relief:

(a) A judgment that the '945 patent claims are not invalid; are not unenforceable; were infringed under 35 U.S.C. § 271(e)(2)(A) by Azurity's submission of its 505(b)(2) Application with a paragraph IV certification; and would be infringed under 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents, by Azurity's manufacture, use, offer to sell, sale, or importation of Azurity's 505(b)(2) Products, including inducement thereof or contribution thereto, prior to the expiration of the '945 patent;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) requiring that the effective date of any FDA approval of Azurity's 505(b)(2) Application be no earlier than the expiration of the '945 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(c) An Order permanently enjoining Azurity; its affiliates, subsidiaries, and/or officers, agents, servants, and employees; and those acting in privity or concert with Azurity, from making, using, offering to sell, selling, or importing Azurity's 505(b)(2) Products until after the expiration of the '945 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(d) Damages or other monetary relief, including costs, fees, pre-judgment interest, and/or post-judgment interest, to Plaintiffs if Azurity engages in commercial manufacture, use, offer to sell, or sale in the United States, or the importation into the United States, of Azurity's 505(b)(2) Products prior to the expiration of the '945 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, as well as any damages or other monetary relief on the basis that this is an exceptional case; and

(e) Such further and other relief as this Court deems proper and just.

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